



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services delegates to the Food and Drug Administration (FDA) Commissioner the authorities vested in the Secretary of Health and Human Services (the Secretary) under section 3855 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, as amended, to send annual letters to Congress regarding the progress of FDA in: evaluating the Over-the-Counter Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use with respect to children under the age of 6, and as appropriate, revising that monograph through the order process of section 505G(b) of the Federal Food, Drug, and Cosmetic Act to address such children. These authorities may be redelegated. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary.

DATES: This authority delegation was approved by the Secretary on February 22, 2023.

Dated: February 22, 2023.

Xavier Becerra,

Secretary,

Department of Health and Human Services.